

Message

From: Karen Hammerstrom [Hammerstrom.KarenLNDU@usepa.onmicrosoft.com]
Sent: 3/17/2011 3:28:54 PM
To: Vandenberg, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcae2b98a04540fb8d099f9d4dead690-Vandenberg, John]
CC: Flowers, Lynn [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1a4411c874d041b9a8badfc32b91bd70-Flowers, Lynn]; Debra Walsh [Walsh.DebraLNDU@usepa.onmicrosoft.com]; Gift, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=746b029cd80e437d9f62708c339a9ec8-Gift, Jeff]; Sams, Reeder [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d5b479ccd894cea99ae55df20de6971-Sams, Reeder]; Jones, Samantha [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eac77fe3b20c4667b8c534c90c15a830-Jones, Samantha]; Cogliano, Vincent [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51f2736376ac4d32bad2fe7cfef2886b-Cogliano, Vincent]; Birchfield, Norman [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c910f2fd28414e819b6afe6dda525e9f-Birchfield, Norman]
Subject: Re: Revised draft Methanol IRIS files for sharing with Agency and Interagency reviewers, and next steps for External Peer Review

What is the resolution? Is there going to be a public comment period? I need to know this in order to draft the FRN.

Karen A. Hammerstrom
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From: John Vandenberg/RTP/USEPA/US
To: Lynn Flowers/DC/USEPA/US@EPA
Cc: Debra Walsh/RTP/USEPA/US@EPA, Jeff Gift/RTP/USEPA/US@EPA, Karen Hammerstrom/DC/USEPA/US@EPA, Reeder Sams/RTP/USEPA/US@EPA, Samantha Jones/DC/USEPA/US@EPA, Vincent Cogliano/DC/USEPA/US@EPA, Norman Birchfield/DC/USEPA/US@EPA
Date: 03/10/2011 11:11 AM
Subject: Re: Revised draft Methanol IRIS files for sharing with Agency and Interagency reviewers, and next steps for External Peer Review

Lynn,

Deliberative Process / Ex. 5

john

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Date: 03/10/2011 09:19 AM
Subject: Re: Revised draft Methanol IRIS files for sharing with Agency and Interagency reviewers, and next steps for External Peer Review

John and Vince: This looks like a very good plan to me. I have a couple of thoughts---

Deliberative Process / Ex. 5

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Jones/DC/USEPA/US@EPA
Date: 03/09/2011 12:52 PM
Subject: Revised draft Methanol IRIS files for sharing with Agency and Interagency reviewers, and next steps for External Peer Review

Vince,

Per the decision to move the non-cancer assessment of methanol forward, we have prepared several files (below) and a task order is moving ahead to arrange with a contractor for external peer review.

First, a note was developed to communicate to the Agency and Interagency reviewers the rationale and plan for moving this non-cancer assessment into external peer review. Please revise this as you wish.
[attachment "Draft note to Agency and Interagency Reviewers 03072011.docx" deleted by Lynn Flowers/DC/USEPA/US]

Second, we went through the Charge and draft Toxicological review and deleted any cancer-specific studies as well as the dose-response assessment for cancer. No new studies were added nor was the text revised, except for obvious revisions such as to the document title. Note that in section 4.2.1.3 and elsewhere the oral studies conducted by the Ramazzini Institute of non-cancer outcomes are included for completeness; these studies play no role in the quantitative derivation of the RfC and RfD (the RfC was derived from data published by NEDO (see table 5-4) and the RfD was derived via route-to-route PBPK-based modeling).

It seems appropriate, as a courtesy, to provide a Note and revised Charge and Tox Review to the Agency and Interagency reviewers. Our rationale is that since the previous Charge and Tox review had completed Agency and Interagency review, that there is no need for further review of this subset of information that had previously been fully evaluated by those reviewers.

[attachment "Methanol Tox Review Draft 03082011.docx" deleted by Lynn Flowers/DC/USEPA/US] [attachment "Methanol Proposed Charge to Peer Reviewers 03072011.doc" deleted by Lynn Flowers/DC/USEPA/US]

At some point soon we should also revise the Methanol page on the NCEA website. At present, there is this notice:

[Mar 2011] UPDATE: Following a report from the National Toxicology Program (NTP), EPA has placed the external peer review of the draft IRIS Methanol Toxicological Review on hold. The NTP report (referred to in [EPA's June 15, 2010 press release](#)) recommended that pathology reviews be carried out to resolve differences of opinion in the diagnoses of certain tumors reported in a methanol research study completed by the Ramazzini Institute. Therefore, EPA and the National Institute of Environmental Health Sciences plan to jointly sponsor an independent Pathology Working Group (PWG) review of select studies conducted at the Institute. More information regarding the PWG work will be made publicly available in the near future.

We will look to you to communicate with the Agency and Interagency reviewers as we proceed with preparations for external peer review. And, once a date has been set for the External Peer Review, we will look for help from the IRIS support staff to announce in the Federal Register a 60-day public comment period.

Please let me know if you have any questions or if you would like to discuss this information.

My thanks especially to Jeff Gift and Reeder Sams as they've pulled this information together.

Thanks,
John

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